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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/708,036

02/04/2004

Ashok V. Joshi

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

12/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/708,036	Applicant(s) JOSHI, ASHOK V.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 and 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3, 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 09/03/2008.

Claims 2, and 11-14 have been canceled.

Claims 1, 3-10, and 15-24 are pending.

Election/Restrictions

1. Applicant had elected invention I, and species: Nasicon, water insoluble peroxide, paste in the reply filed on 03/17/2008. Applicant had canceled/deleted non-elected species.

Applicant admits failure to elect species from topical application, wound healing devices, prosthetic devices, and implantable devices. However, applicant had canceled those non-elected species in the reply filed on 03/17/2008.

Applicant submits that claim 15 should have been included by invention I as being generic to the species elected by invention I. However, claim 15 is directed to distinct invention as it does not require the specific support material required by claim 1.

Applicant argues that amended claim 17 is within the scope of elected invention and species. In response to this argument, it is argued that claim 1 and 17 are directed to unrelated inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different

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inventions have different modes of operation because invention of claim 17 is a wound dressing device while invention of claim 1 is not necessary used for wound, it can be used in any other medical application as disinfecting an instrument or surfaces in the operation room or medical offices.

Applicant submits that amended claim 19 is within the scope of elected invention and species because applicant elected paste substrate that embraced semisolid substrate of claim 19. However, claim 19 is directed to distinct invention as it does not require the specific support material required by claim 1.

2. Claims 5-10, 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species.

Claims 1, 3, and 4 are included in the prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,985,388 ('308) in view of the article "Sol-Gel processing of NASICON thin film using aqueous complex precursor" by Shimizu et al. and US 5,656,037 ('037).

US '308 teaches material useful in medical devices such as wound dressing or prepared in ointment, solution or paint, i.e. support and substrate (abstract; col.4, lines 20-23; col.7, lines 11-21, lines 35-42; col.8, lines 17-). The silver oxide deposited with atom molecules of a different material. The different material includes metals such as Ti, Zn, Si, or oxides or halides thereof, that read on reactive material (col.7, lines 11-21) and this reads on the metal ion exchanged membrane.

Although US '308 teaches ion exchange membrane and reactive metal oxides, however, the reference does not explicitly teach Nasicon as a support material or water insoluble peroxide as reactive material as claimed by claim 1.

Shimizu et al. teaches that Nasicon is known to have high ionic conductivity and high chemical stability (introduction).

US '037 teaches insoluble peroxide such as magnesium peroxide deposited on natural and synthetic substrates because insoluble peroxides show bactericidal effect and inhibit growth and spread of odor and disease-causing gram-positive and gram-negative bacteria (abstract; col.9, line 29-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device such as wound dressing comprising support and metal oxide deposited on the support by ion exchanged forming ion exchange membrane as disclosed by US '308, and replace the support with Nasicon because Nasicon disclosed by Shimizu to have high ionic conductivity and high chemical stability, and further replace the metal oxide with insoluble peroxides because US '037 teaches insoluble peroxides show bactericidal effect and inhibit growth and spread of odor and disease-causing gram-positive and gram-negative bacteria, with reasonable expectation of having medical devices comprising support of Nasicon and insoluble peroxide deposited on the support wherein the device shows chemical stability and effective bactericidal effect, such characters are desirable for medical devices.

Response to Arguments

6. Applicant's arguments filed 09/03/3008 have been fully considered but they are not persuasive.

Applicant argues that Claim 1, 3, and 4 would not have been obvious from the combined teachings of Burrell '308, Shimizu, and Vigo. Applicant argues that Burrell '308 "does not explicitly teach Nasicon as a support material or water insoluble peroxide

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as reactive material as claimed by claim 1. Applicant argues that Shimizu neither teaches a water insoluble peroxide associated with Nasicon nor suggests the possibility of associating a water insoluble peroxide associated with Nasicon in a beneficial material for medical application. Merely because Nasicon is a known material does not mean that it would have been obvious to associate a water insoluble peroxide with Nasicon. Furthermore, because the water insoluble peroxides recited in claim 1 are not "ions", the high ionic conductivity of Nasicon is not a relevant "reason" to rely upon Shimizu to support the rejection of claim 1. Applicant argues that Vigo only discloses applying magnesium peroxyacetate or magnesium dihydroperoxide to fibrous substrates.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). US '308 teaches material useful in medical devices such as wound dressing comprising support and/or substrate and silver oxide deposited with atom molecules of a different material. The different material includes metals such as Ti, Zn, Si, or oxides or halides thereof. Shimizu is relied upon for the solely teaching of specific support material or substrate, that is Nasicon, and Vigo is relied upon for the solely teaching of compounds comprising water insoluble peroxides for their antibacterial effects. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art

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would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). The invention as a whole is taught by the combination of the three references. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues that the Examiner does not identify any teaching or suggestion or reason why a person having ordinary skill in the art would replace Vigo's fibrous substrate with the elected paste substrate (claim 3). Moreover, Vigo fails to contain any teaching, suggestion, reason, or expectation of success that its magnesium peroxyacetate or magnesium dihydroperoxide compounds may be associated with a Nasicon support material.

In response to this applicant's argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the

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prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device such as wound dressing comprising support and metal oxide deposited on the support by ion exchanged forming ion exchange membrane as disclosed by US '308, and replace the support with Nasicon disclosed by Shimizu and further replace the metal oxide with insoluble peroxides because US '037. One would have been motivated to do so because Shimizu teaches that Nasicon has high ionic conductivity and high chemical stability, and because US '037 teaches that insoluble peroxides show bactericidal effect and inhibit growth and spread of odor and disease-causing gram-positive and gram-negative bacteria. One would reasonably expected formulating medical devices comprising support of Nasicon and insoluble peroxide deposited on the support wherein the device shows chemical stability and effective bactericidal effect, such characters are desirable and beneficial for medical uses.

It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of

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elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have *prima facie* been obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argues that neither Burrell '308, Shimizu, nor Vigo teaches a "paste" substrate recited in claim 3. Applicant argues that Burrell '308 discloses a silver "suspension" that includes the complex silver ions disclosed therein, a person having ordinary skill in the art will recognize that a suspension is not a paste that is understood to include a mixture of a soft and malleable consistency.

In response to this argument, applicant's attention is directed to the disclosure of US '308, at col.7, lines 38-40, wherein the reference clearly teaches ointment. Ointment reads on paste, in absence of specific definition of the composition of the paste. Ointment is soft and malleable consistency. The references are evaluated by all they suggest to one versed in the art.

Applicant argues that neither Burrell '308, Shimizu, nor Vigo teaches the disclosed water insoluble peroxides (MgO_2 , BaO_2 , SnO_2 , AgO , CaO_2 , CuO_2 and ZnO_2) associated with the support material. Vigo's magnesium peroxyacetate or magnesium dihydroperoxide are distinctly different.

In response to this argument, applicant's attention is directed to the language of claim 4 that recites "water insoluble peroxides comprise", and that encompasses compounds comprising one of MgO_2 , BaO_2 , SnO_2 , AgO , CaO_2 , CuO_2 and ZnO_2 . Magnesium peroxyacetate and magnesium dihydroperoxide disclosed by Vigo are compounds comprising MgO_2 , thus read on claim 4.

7. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,333,093 ('093) in view of the article "Sol-Gel processing of NASICON thin film using aqueous complex precursor" by Shimizu et al. and US 5,656,037 ('037).

US '093 disclosed wound dressing where the skin contacting surface comprises substrate associated with metal selected from the group comprising silver (abstract; col.3, lines 1-7; col.5, line 40). The skin-contacting layer comprises matrix that incorporates the silver oxide deposited with atom molecules of a different material. The different material includes metals such as Ti, Zn, Si, or oxides or halides thereof (col.3, lines 8-13); and this reads on the metal ion exchanged membrane.

Although US '093 teaches ion exchange membrane and reactive metals, however, the reference does not explicitly teach Nasicon as a support material or water insoluble peroxide as reactive material as claimed by claim 1.

Shimizu et al. teaches that Nasicon is known to have high ionic conductivity and high chemical stability (introduction).

US '037 teaches insoluble peroxide such as magnesium peroxide deposited on natural and synthetic substrates because insoluble peroxides show bactericidal effect and inhibit growth and spread of odor and disease-causing gram-positive and gram-negative bacteria (abstract; col.9, line 29-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device such as wound dressing comprising support and reactive metals deposited on the support by ion exchanged forming ion exchange membrane as disclosed by US '093, and replace the support with Nasicon because Nasicon disclosed by Shimizu to have high ionic conductivity and high chemical stability, and further replace the metal oxide with insoluble peroxides because US '037 teaches insoluble peroxides show bactericidal effect and inhibit growth and spread of odor and disease-causing gram-positive and gram-negative bacteria, with reasonable expectation of having medical devices comprising support of Nasicon and insoluble peroxide deposited on the support wherein the device shows chemical stability and effective bactericidal effect, such characters are desirable for medical devices.

Response to Arguments

8. Applicant's arguments filed 09/03/3008 have been fully considered but they are not persuasive.

Applicant argues that claims 1, 3, and 4 would not have been obvious from the combined disclosure of Burrell '093, Shimizu, and Vigo for the same reasons discussed above in relation to the Burrell '308 primary reference. Applicant argues that Burrell 093 does not explicitly teach Nasicon as a support material or water insoluble peroxide as reactive material as claimed in claim 1. To compensate for the deficiency of Burrell '093, the Office Action cites the Shimizu and Vigo secondary references for the purpose of teaching the missing claim elements in the same manner discussed above.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). US '093 teaches material useful in medical devices such as wound dressing comprising support and/or substrate and silver oxide deposited with atom molecules of a different material. The different material includes metals such as Ti, Zn, Si, or oxides or halides thereof. Shimizu is relied upon for the solely teaching of specific support material or substrate, that is Nasicon, and Vigo is relied upon for the solely teaching of water insoluble peroxides for their antibacterial effects. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in

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the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). The invention as a whole is taught by the combination of the three references. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Further, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device such as wound dressing comprising support and metal oxide deposited on the support by ion exchanged forming ion exchange membrane as disclosed by US '093, and replace the support with Nasicon disclosed by Shimizu and further replace the metal oxide with insoluble peroxides because US '037. One would have been motivated to do so because Shimizu teaches that Nasicon has high ionic conductivity and high

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chemical stability, and because US '037 teaches that insoluble peroxides show bactericidal effect and inhibit growth and spread of odor and disease-causing gram-positive and gram-negative bacteria. One would reasonably expected formulating medical devices comprising support of Nasicon and insoluble peroxide deposited on the support wherein the device shows chemical stability and effective bactericidal effect, such characters are desirable and beneficial for medical uses.

It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have *prima facie* been obvious within the meaning of 35 U.S.C. 103 (a).

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,267,782 disclosed medical articles with adhered antimicrobial elemental metals.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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